CONMED LINVATEC
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MAR 2 9 2013

510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K130497

Date Prepared: 28-Mar-2013

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Jonathan Werner
Regulatory Affairs Manager
Telephone (727) 399-5574
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C. Device Name

Trade Name:	D4000 Drive System, D4000A Drive System with Irrigation
Common Name:	Drive System
Classification Names:	Electric cranial drill motor. (882.4360)
Proposed Class/Device:	Class II
Product Codes:	HBC, GEY, ERL

D. Predicate/Legally Marketed Devices

Device Name:	Advantage Turbo Drive System
Company Name:	ConMed Linvatec
510(k) #:	K050519

E. Device Description

The D4000/D4000A Drive System console functions as a powered instrument console for driving powered instruments and accessories used in the cutting of soft tissue and bone at the surgical site.

The D4000/D4000A Drive System console is a non-sterile device and must be located in a non-sterile area of the operating suite. Additionally the D4000A console offers an irrigation pump that, when used with tubing sets, provides a sterile fluid supply to the blades, burs, and drill bits, at the surgical site, for lavage and cooling. The handpiece, handpiece cord, and irrigation tube sets are sterile. The handpiece is used in the sterile field with the cord connected to the console. The irrigation tube set is used on the handpiece in the sterile field with the cassette connected to the console. The footswitch is non-sterile and placed on the floor.

The console provides two handpiece drive ports that are used with a variety of handpieces. Handpiece functionality can be controlled directly by the handpiece, and/or by a corded footswitch or wireless footswitch.

Handpiece speed, direction, user settings, irrigation flow rate, and footswitch settings are controlled with the touch-screen displays.

The D4000/D4000A is a rebranded update to the Advantage Turbo Drive System (D3000), which shares the same intended use, indications for use, conditions of use, and fundamental scientific technology with the predicate device. The D4000/D4000A powers a reduced set of the same handpieces, to the same performance specifications, as the D3000. Where applicable, these handpieces can also be activated by the same footswitches used in the previous system.

The D4000/D4000A software was rewritten in order to accommodate the new internal circuitry layout and to support additional integrated components (i.e. touchscreens, wireless footswitch transceiver, etc.) as well as to send direct signal to 24k when shaver is operating.

Further, the D4000 and D4000A are the same device except for the fact that, like the D3000, the D4000A incorporates a low-flow pump for the purpose of optional handpiece irrigation. The D4000A also includes a "Prime Button" on the front panel that is associated with the low-flow pump.

F. Testing

The verification and validation testing of the D4000/D4000A Drive System included Electrical Safety, EMC, software, system integration, labeling, and packaging/transportation qualifications.

G. Intended Use / Indications

The D4000/D4000A System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurological, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive, and Spinal surgical procedures.

H. Substantial Equivalence

The D4000 Drive System/D4000A Drive System with Irrigation has the same intended use, same conditions of use, and utilizes the same fundamental scientific technology as the predicate device, while raising no new issues of safety or effectiveness. The D4000/D4000A is therefore substantially equivalent to the Advantage Turbo Drive System cleared by K050519.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Linvatec Corporation D/B/A Conmed Linvatec
% Mr. Jonathan Werner, RAC
Regulatory Affairs Manager
11311 Concept Boulevard
Largo, Florida 33773

April 23, 2013

Re: K130497
Trade/Device Name: D4000 Drive System/D4000A Drive System with Irrigation
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill monitor
Regulatory Class: II
Product Code: HBC, GEY, ERL
Dated: February 25, 2013
Received: March 01, 2013

Dear Mr. Werner:

This letter corrects our substantially equivalent letter of March 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130497

Device Name: D4000 Drive System / D4000A Drive System with Irrigation

Indications For Use:

The D4000/D4000A System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurological, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive, and Spinal surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S For

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130497